ADVIL COLD AND SINUS- ibuprofen, pseudoephedrine hydrochloride capsule, liquid filled GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

ACTIVE INGREDIENTS (IN EACH LIQUID-FILLED CAPSULE)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt)

Pseudoephedrine HCl 30 mg

*nonsteroidal anti-inflammatory drug

PURPOSES

Pain reliever/fever reducer

Nasal decongestant

USES

temporarily relieves these symptoms associated with the common cold or flu:

- headache
- fever
- sinus pressure
- nasal congestion
- minor body aches and pains

WARNINGS

Allergy alert:

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- in children under 12 years of age
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other product that contains pseudoephedrine or any other nasal decongestant
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better

- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- symptoms continue or get worse
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years of age and over:
 - take 1 capsule every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 capsule, 2 capsules may be used.
 - do not use more than 6 capsules in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use

OTHER INFORMATION

- each capsule contains: potassium 20 mg
- store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep carton.

INACTIVE INGREDIENTS

D&C yellow no. 10, FD&C red no. 40, gelatin, medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution

QUESTIONS OR COMMENTS?

Call weekdays 9 AM to 5 PM EST toll free at 1-800-88-ADVIL

PRINCIPAL DISPLAY PANEL

 $\mathbf{Advil}^{\mathbb{R}}$

COLD & SINUS Non-Drowsy

Ibuprofen 200 mg 🛘 Pain Reliever/Fever Reducer (NSAID)

Pseudoephedrine HCl 30 mg [] Nasal Decongestant

Relieves Sinus Pressure, Nasal Congestion and Fever

LIQUI-GELS®

32 LIQUID-FILLED CAPSULES

STAD-INDIT COLD & SINUS

- children under 12 years of age: do not use miess dieded by a doctor
- do not use more than 6 espeules in any 24-hour period It symptoms do not necpond to 1 capada, 2 capadas may
- adults and children 12 years of age and over:
 Eake 1 capsule every 4 to 6 hours while symptoms persist.
 - be au ed bituoria eaco evitaelle Jaellaria ert m bataerib neif enom salst lee ob .
 - Directions

gund yards (couguned)

- TIADY-89-009-1 18 #4 HRI 153 Checklons or comments? (st western from 9 mm 6 PM
- glycof, potassium hydroxide, purfiled water, sorbidol sorbitan obludon teagh" wegnun-quain gittiyosuges" busilusosogos ing botkegi keue Inactive ingredients Dac yelow oc. 10, FDBC red no. 40,
- m read all vermings and directions belone use. Keep carbon. (H-901) 3.05 avode learl aviazona blovA. (H-11-88) 3.65-05 is entre at m each catego contains: begassinm 50 mg
 - Other information
 - Drug Facts (continued)

- Впор лекдо Аве бируез ш
- m biking sepiriot heart addeds or stroke, because Bugrorien may, decrease this benefit to aspirio
- THE SHOULD NO ISSUE m paying any other product that contains pseudosphedrins or any other
- mineger a doctor's care for any serious condition ens unyli eeu enoled krisemanty so sakob s AsA.
 - agoungs a duppy over no 6 m
 - due to an entarged processe gland, or had a stroke
- you have high blood pressure, heart cleases, hwy cirrhosts, lodery desise, asthers, thyrold cleases, cabbes, rave brouble strains.
 - mindheed selfous, ameldong floemots to yook iff a evert wey. or fever reducers
- myou have problem or seneus side effects from talking parties as m szowecz pjeegyű marwyd stopjee po kon
- Meas onelad retoob 6 AsA an MM-UL, ask a doctor or pharmacist before taking this product. banditions, or Parlaments for depression, psychiatric, or emotions conditions, or Parlament's desces), or for 2 weeks after stopping conditions, or Parlament a notice of the properties of the description of up on the pro-
 - i kee sus uow zeptő s basoubgos mouceaujus orapses japippor.
 i dáy; pajoss or syor yeary sruboù.

 - beginned avoid a sold in the in drilden under 12 years of age if you have ever had an alwayic reaction to any other
- esu ion oli that is higher throu use more than directed or for longer than directed. they or meant attack, heart failure, and stroke, these can be fatal, the Hoart attack and sholos warning: NSAIDs, except aspirin, incr
 - Drug Facts (continued)

- Уеме рави вирост колостионный егридног во dieu complications during definery.

 Assert at resets of children, in case of overdose, get medical googs, pecanee it way caree buogewerings autoom cand or
- ner jule expectativity important for the buryon during the last audyod lessons aloud aftern a size, aprilosof iz sond no insengend if
 - readde sincodurés was Aus m a you get nervous, dizzy, or skepkess
 - care injujed out ut pursuid a full two to see upon m minest congestion lasts for more than 7 days symptoms confinue or get worse
 - m fever gets worse or fasts more than 3 days
 - m jed swej pû ∎ gritteg steec µ
 - chest pain bouble broading wookness in one part or side of body
 - Уол узум вумиротья от веят риобенть от втоюх ■ lave shreek pain that does not get better
 - stocts эстар то √роом вият **ш** boold imov =
- 加高洲 m han extensions ask of the following signs of stomach bleeding Stop use and ask a dector f
 - m race with 1000 or might I stomeon ribes (occurs
 - to unborne stiff gritte mod W
 - Drug Facts (continued)

- m minor body sches and pains
 - uopseõuoo pisseu

 euroseud snups
- m headache im fever
- USBS temporarily relevant these symptomes associated with
- Brub Austrumethil-the lebioretanon THE SECURITION DESERVE
- (flas mulasstog bris blos eert anti as frivaeng) Ø. pin OC 10H en hbertgeobuwe?
- Rouber revel/neveiler nis⁴. Sco mg loupraten (NSALD)". corrente unoudro poznanos
- (yu escy jydnig-yjjeg csbanje)
- sasodmd Active ingredients
 - Drug Fads
- biss more or for a longer time than directed Septifit, Ibuprofen, naprosen, or odhers Buse S or more abbloit dirinks every day within seing this product m pays other drugs con bining prescription or nonprescription NEALDs
- бир роже зо (дентреорые) биния роже в ежд в
- If an alkegic needed no account, also pues and seak medical high might have.

 Storage beliefing warming for the conduct confidence in RASAD, which may be desired a first broad control and seaking if the channels is highest if your course exercise between about such that have bed advantal above out to broad the problems.

 The problems is broad that the confidence in the conduction of the channel and the confidence in the co
- Vijetů) sjed; (pobucjeu wsk carae a severe sijetů)o resigiou' esbecjají). **egninisW**
 - Drug Facts (continued)

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

COLD & SINUS Non-Drowsy

|buprofen 200 mg > Pain Reliever/Fever Reducer (NSAID) Pseudoephedrine HCl 30 mg > Nasal Decongestant

Relieves Sinus Pressure, Nasal Congestion and Fever LOUILGEES Advil

32 LIQUID-FILLED CAPSULES





ADVIL COLD AND SINUS

ibuprofen, pseudoephedrine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-0184
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients		
Ingredient Name	Strength	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PO TASSIUM HYDRO XIDE (UNII: WZH3C48 M4T)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6O92ICV9RU)		

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	OVAL	Size	15mm	
Flavor		Imprint Code	Advil;C;S	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0184-32	32 in 1 CARTON	05/30/2002	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0573-0184-16	16 in 1 CARTON	05/30/2002	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021374	05/30/2002	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Registrant - Pfizer Inc (113480771)

Revised: 11/2020 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC